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09/602,740	06/23/2000	Markus Pompejus	BGI-126CP	1632

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EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/602,740	Applicant(s) POMPEJUS ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *18-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5-9 and 25-38* is/are rejected.

7)☒ Claim(s) *1,3,4 and 10-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (Paper No. 9 mailed on January 29, 2002), Applicants filed an election and an amendment (Paper No. 10) to the claims. Claims 1-7 and 35-38 have been amendment. Claims 1-38 are pending in the instant application.

Election

2. Applicant's election with traverse of SuperGroup A, Claims 1-17 and 36-38, and SEQ ID NO:1 (Group) in Paper No. 10 is acknowledged. Applicants do not traverse the SuperGroup divisions; Applicants do traverse the division within SuperGroup A limiting to a genus relating to one particular SEQ ID NO.

The traversal is on the ground that "a reasonable number of sequences are allowed to be claimed in a single application", particularly up to 10 sequences. This is not found persuasive because for the following reasons. The MPEP states that "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction" (see M.P.E.P. § 803.04). That is to say that SEQ ID NOs: 1, 3, 5, 7, 9, 13, 15, 17, 19, and 21 could be examined together without undue burden. However, the instant claims are drawn to a **genus** of DNA (not just SEQ ID NO:1) by virtue of the hybridizing language, 50% identity language, 15 nucleotide fragment language, and protein encoding language. Particularly, any DNA which encodes the polypeptides (encoded by the above SEQ ID NOs), which polypeptides are SEQ ID NOs: 2, 4, 6, 8, 10, 14, 16, 18, 20, and 22, is not included in this group; the search for a specific

nucleic acid sequence is different from the search for all possible nucleic acid sequences encoding a particular protein, even if that protein is encoded by the original nucleic acid sequence. Thus, a complete search of the DNA is a search of not only the DNA that is SEQ ID NO:1, but also a search of other DNAs encoding SEQ ID NO:2 as well as all the DNAs within the variation (hybridization, fragment, % identity) language. Moreover, these distinct genes encode distinct proteins and the MPEP states that "nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another" (see M.P.E.P. § 803.04).

The traversal is also on the ground that an election of species is more appropriate for the given subject matter. This is not found persuasive because an election of species is only proper when generic subject matter is reasonably searchable. In the instant case, the only relationship the "species" have with each other is that they are DNA and that they are from *C. glutamicum*. No generic DNA sequence is disclosed, nor can the Examiner readily identify one for searching purposes.

The traversal is also on the ground that no serious search burden exists for the Examiner to examine DNAs relating to more than one SEQ ID NO. This is not found persuasive for the following reasons. Each additional SEQ ID NO requires a distinct search or searches in the sequence databases at the Patent and Trademark Office; such searches require computer time that increases exponentially with the number of nucleotides of DNA needing to be searched. These searches are, in no way, co-extensive, unless the DNAs have related domains that can be searched instead of the entire sequence; this is not the case here. Moreover, each new SEQ ID NO requires a search in textual databases using keywords. These searches are, in no way, co-

extensive, unless the DNAs encode proteins having the same, or similar, functions. That is not the case here.

The requirement is still deemed proper and is therefore made FINAL.

Due to the likelihood of allowable subject matter relating to SEQ ID NOs:1/2, the Examiner will rejoin Claims 25-35 in the instant Office action for the purposes of compact prosecution. Thus, Claims 18-24 remain withdrawn from consideration as non-elected inventions, and Claims 1-17 and 25-38 will be examined herein as they relate to the elected subject matter of SEQ ID NOs:1/2.

Priority

3. The instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/141,031, filed on June 25, 1999, 60/143,208, filed on July 9, 1999, and 60/151,572, filed on August 31, 1999, as requested in the declaration and the first lines of the specification.

4. Acknowledgment is made of applicant's claim for foreign priority based on applications (27 total) filed in Germany. It is noted, however, that applicant has not filed certified copies of the German applications as required by 35 U.S.C. § 119(b).

Information Disclosure Statement

5. No information disclosure statement has been filed with the instant application as of the date mailed of the instant Office action. Applicants are reminded that they have a duty to disclose all information, of which they are aware, relevant to the patentability of the pending claims (see 37 C.F.R. § 1.56 and M.P.E.P. § 2000).

Objections to the Specification

6. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter. It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the definition of "SMP" for completeness.

7. The title is objected to for not adequately describing the claimed subject matter. The Examiner suggests the following new title:

---Polynucleotides Encoding a 6-Phosphoglucolactonase from *Corynebacterium glutamicum*---

8. The specification is objected to for missing Appendix A and Appendix B. These appendixes are referred to throughout the specification. In Applicant's transmittal letter from June 23, 2000, Appendix A is noted as containing 156 pages and Appendix B is noted as containing 52 pages. Applicants state that said appendixes have been submitted; however, no appendixes are in the file.

Since Applicants' provisional applications contain appendix data and since they are expressly incorporated by reference, Applicants can amend these appendixes into the specification by way of amendment in response to the instant Office action. Alternatively, Applicants can submit documentation to prove that Appendix A and Appendix B were submitted with the instant application on June 23, 2000 as noted in the transmittal to support their insertion. An amendment is required to include Appendix A and Appendix B in the file.

9. The specification is objected to for being confusing in its description of SEQ ID NOs: 1/2 as described in Table 1. This open reading frame is described as having "6-phosphoglucolactonase" function. No definition of this enzymatic function is found in the art. The Examiner did find 6-phosphoglucon**o**lactonase (see attached result set form the Registry database). Appropriate clarification and, possibly, amendment to the specification is required. The Examiner notes that no explanation of the function listed in Table 1 had been disclosed at the time of filing. Therefore, it is wholly unclear whether the function is Table 1 is a typographical error or a novel function found in *C. glutamicum*.

Claim Objections

10. Claims 1-17 and 25-38 are objected to for containing non-elected subject matter. All reference to SEQ ID NOs: 3/4, 5/6, 7/8, 9/10, 13/14, 15/16, 17/18, 19/20, and 21/22 must be deleted. The pending claims will be examined has if this correction has been made. Appropriate amendment or petition is required.

11. Claim 2 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The further limitation added in Claim 2 is an inherent feature in the subject matter of Claim 1 since all the genes in Table 1 are disclosed as encoding SMP polypeptides. Appropriate amendment and/or clarification is required.

12. Claims 15 and 30 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Because of the breadth of the term "modulation" and since expression of 6-phosphogluconolactonase will affect the production of chemicals in the host cells, this "modulation" limitation does not further limit the subject matter of the parent claim effectively. Appropriate amendment and/or clarification is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 2, 8, and 34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The abbreviation "SMP" is used in Claim 2 without appropriate definition upon its first appearance in the claims. The Examiner suggests replacing "SMP polypeptide" with -sugar metabolism and oxidative phosphorylation (SMP) polypeptide-.

14. Claims 8 and 34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 8, the term "stringent conditions" in reference to hybridization conditions is unclear. On page 28 of the instant specification, preferred embodiments are described for "stringent conditions" but a precise definition is not clear. Appropriate amendment is required.

15. Claims 25-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reference to the "vector of claim 12" is improper since Claim 12 is drawn to a host cell. The appropriate claim would seem to be Claim 11. The instant claims will be examined as is Claim 25 depends from Claim 11. Appropriate amendment is required.

16. Claims 29 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The various genus/species names are unclear for the following reasons:

a) "*Corynebacterium, lilium*" should not be separated by a comma.

b) "*Brevibacterium parraffinolyticum*" is misspelled and should be ---parrafinoliticum---.

c) *Brevibacterium divaricatum* and *Brevibacterium lactofermentum* are synonyms of *Corynebacterium glutamicum* (see attachment) and are inappropriate alternatives in a Markush group whose members must all be distinct.

d) *Brevibacterium healii, Brevibacterium ketoglutamicum, and Brevibacterium paraffinoliticum* are synonyms of *Rhodococcus erythropolis* (see attachment) and are inappropriate alternatives in a Markush group whose members must all be distinct. All but one of the three noted must be removed.

e) *Corynebacterium acetoglutamicum*, *Corynebacterium fujiokense*, *Corynebacterium nitrilophilus*, and *Corynebacterium butanicum* are unknown genus/species organisms.

The Examiner requests explanation of these genus/species and/or amendment to the claims.

17. Claim 38 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "regulatory region" of the gene that encodes SEQ ID NO:2, described as SEQ ID NO:1, is wholly unclear. No promoter or enhancer region is described in the specification or the art; these are typical regulatory regions. Clarification of the instant claims is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 5-8 and 34 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 5 is drawn to DNA encoding allelic variants of SEQ ID NO:2 that hybridize to SEQ ID NO:1, Claim 6 is drawn to DNA having at least 50% identity with SEQ ID NO:1, Claim 7 is drawn to DNA comprising at least a 15-mer fragment of SEQ ID NO:1, and Claim 8 is drawn to DNA that hybridizes to any of the foregoing DNAs. None of these claims include a function with the claimed structure.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject

matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses DNAs relating to SEQ ID NOs:1/2 encoding polypeptides that function as 6-phosphoglucolactonases (see specification objection above concerning enzyme name and function in Table 1). Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations (i.e., having 6-phosphoglucolactonases function). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations.

The Examiner suggests the insertion of a functional limitation on the polynucleotides in the genus of Claims 5-7. However, due to the confusion of the function as noted above in the objection to the specification concerning the possible typographical error in Table 1, the assignment of a clear function to SEQ ID NO:1 and DNAs encoding SEQ ID NO:2 may be problematic since said function requires support in the specification as originally filed.

19. Claims 36 and 37 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 36 and 37 are drawn to host cells containing modified DNA, by disruption or modification, related to SEQ ID NO:1. None of these claims include a function with the claimed structure.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses DNAs relating to SEQ ID NOs:1/2 encoding polypeptides that function as 6-phosphoglucolactonases (see specification objection above concerning enzyme name and function in Table 1). Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations

(i.e., having 6-phosphoglucolactonases function). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations.

20. Claim 38 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 38 is drawn to a host cell comprising SEQ ID NO:1 with a modified regulatory region. This claim does not include a function with the claimed structure.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses DNAs relating to SEQ ID NOs:1/2 encoding polypeptides that function as 6-phosphoglucolactonases (see specification objection above concerning enzyme name and function in Table 1). Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations (i.e., having 6-phosphoglucolactonases function). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations.

21. Claims 6-8 and 34 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides with at least, for example, 90% sequence identity to a polynucleotide which encodes SEQ ID NO:2, does not reasonably provide enablement for polynucleotides with such low sequence identity, such as the 50% identity claimed or the 15-mer fragment claimed using comprising language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The amount of experimentation required of one of skill in the art to use the claimed invention to the full extent of its scope is undue.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404).

Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

Applicants present no guidance or working examples of the use of polynucleotides that have such low sequence identity with respect to SEQ ID NO:1. The nature of the invention is such that the DNA encodes a functional protein, a 6-phosphoglucolactonase useful in promoting fine chemical biosynthesis in *C. glutamicum*; and with such a great deviation from the known sequence, the predictability of functionality becomes extremely low. Such enormous breadth and unpredictability renders the instant claims not enabled to the full extent of their scope without undue experimentation.

22. Claim 35 is rejected under 35 U.S.C. § 112, first paragraph, enablement, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 35 is drawn to diagnosing the presence or activity of *C. diphtheriae* using a screen utilizing a DNA from *C. glutamicum*. While it would be common in the art to screen for

C. glutamicum presence with a DNA from *C. glutamicum*, one of skill in the art would be required to perform undue experimentation to (1) screen for *C. diphtheriae* or (2) screen for activity using DNA).

The factors to be considered in determining whether undue experimentation is required are summarized above.

The specification provides no guidance or working examples of screening for *C. diphtheriae* presence using SEQ ID NO:1. The nature of the invention is such that if *C. diphtheriae* has a 6-phosphogluconlactonase gene, it is unpredictable whether or not such a gene could be detected by SEQ ID NO:1, a 6-phosphoglucolactonase gene from another species. The state of the prior art is such that genes from a specific species are commonly used to detect the presence of the species, in a host organism for example; however, detecting varying species is not typical practice. Moreover, a method using the claimed method steps cannot, without undue experimentation, detect the activity of any organism, either *C. glutamicum* or *C. diphtheriae*; an enzyme activity, or some other assay, would be required to assay for activity. Thus, Claim 35 lacks enablement as supported by the specification as originally filed and the art at the time of the invention.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 7 and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Marra *et al.* (GenBank Accession Number AA915356 (April, 1998) vz29z08.r1 Soares_thymus_2NbMT *Mus musculus* cDNA clone). The instant claims are drawn to nucleic acid molecules comprising a 15-mer fragment of SEQ ID NO:1.

Marra *et al.* teach a 456 nucleotide mRNA whose nucleotides 386-366 are identical to SEQ ID NO:1 from 792-812 (see attached alignment).

24. Claim 9 is rejected under 35 U.S.C. § 102(b) as being anticipated by Ma *et al.* (Cloning and Characterization of the *Pseudomonas aeruginosa zwf* Gene Encoding Glucose-6-Phophate Dehydrogenase, an Enzymes Important in Resistance to Methyl Viologen (Paraquat) J. Bacteriol. (April, 1998) 180(7):1741-1749). The instant claims is drawn to a DNA that is a portion of SEQ ID NO:1 connected to a sequence encoding a heterologous polypeptide.

Ma *et al.* teach the zwf gene that is later renamed to the *Pseudomonas aeruginosa* pgl gene which is analgous to the devB gene for 6-phosphogluconolactonase. The gene taught by Ma *et al.* readily contains a portion of SEQ ID NO:1, since no limitation on how small the portion can be is noted in the claims. And *zwf* encodes a heterologous polypeptide.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. § 101.

25. Applicant is advised that should Claim 1 be found allowable, Claims 2 and 3 will be objected to under 37 C.F.R. § 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See M.P.E.P. § 706.03(k). For Claim 2, the further limitation of "SMP" polypeptides is contained in Claim 1 (see claim objection above for not further limiting the subject matter). For Claim 3, the fact that the DNAs are *C. glutamicum* in origin is also inherent in Claim 1 that is drawn to the exact sequence.

Noteworthy Art

26. The following are noted references not used in art rejections above.

a) Krubasik *et al.* GenBank Accession Number NP_600792 (March ,2001) 6-phosphogluconolactonase/Glucosamine-6-phosphate isomerase/deaminase. A 235 amino acid protein from *C. glutamicum*.

b) EP 1108790 A2. Nakagawa *et al.* published June 20, 2001 with earliest priority to December 16, 1999. SEQ ID NO:1 is identical to SEQ ID NO:7064 in EP document (see attached alignment).

c) WO 01/04322 A1. Dunican *et al.* published January 18, 2001 with earliest priority to July 9, 1999. SEQ ID NO:1 is identical to SEQ ID NO:1 (*devB* gene) in WO document (see attached alignment).

Conclusion

27. Claims 1, 3, 4, 10-17 are objected to in the Office action; Claims 2, 5-9, and 25-38 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK
April 21, 2002